REMARKS

The withdrawn species claims have been retained and it is respectfully submitted that they can be restored to active status in light of the allowability of the remaining claims, as discussed below.

Claims 1, 2, 10, 12 and 13 have been rejected as obvious under 35 U.S.C. § 103 over the combination of Young in view of the newly cited Peters reference. This rejection is respectfully traversed.

As pointed out on page 4 of the application, the use of a selective estrogen receptor modulator (SERM) in hormone replacement therapy (HRT) was known prior to the present invention. That fact is acknowledged in the preamble of the Jepson claims of this case. As is also known, HRT is administered to women who have gone through or are going through menopause, an event which causes infertility as a result of normal aging, i.e., the women are or are about to be infertile. It is also explained on pages 1-3 of the application, the SERMs have their own side effects, one of which is bleeding. The presently claimed invention is based on improving the known HRT method using a SERM by additionally administering an agent which exhibits progestogenic activity to the woman receiving HRT in an amount effective to modulate the side effects of the SERM.

The Young reference teaches the use of a SERM in HRT. Accordingly, Young simply teaches the method which is being improved in the present invention, i.e., the method set forth in the preamble of the instant claims. There is no teaching or suggestion of combating the side effects of the SERM in this reference. Since there is no

teaching or suggestion the side effects of the SERM, there is also no motivation to address them.

The Peters reference indicates in the Background of the Invention section, that use of steroids in the control of, e.g., menstrual cycles, is known and that progestins such as levonorgestrel have been used for a variety of purposes, including "control of uterine bleeding". While the meaning of "control" is not discussed in the reference, it is apparent from the fact that the cited passage is sandwiched between a paragraph referring to menstruation and a paragraph referring to contraception, that what may be controlled is normal uterine bleeding. There is no reference in Peters to HRT and clearly, therefore, addressing uterine bleeding which is a side-effect of a SERM administered in the course of HRT is not contemplated.

It is respectfully submitted that the broad and undefined reference to "control of uterine bleeding" in Peters perhaps might make it obvious to try to employ a progestin in connection with a SERM HRT procedure in order to determine if such usage would address the bleeding side effect of the SERM. Peters teaches in column 2 that progestins per se can have an estrogenic or anti-estrogenic effects. When added to a SERM, as proposed in the rejection, will they impart an estrogenic effect, and thereby make the bleeding worse, or not? There is no basis for conjecture. Peters indicates that the new compounds of that invention have minimal effect on ancillary hormonal activity and that would imply that even if the SERM would be considered to provide some type of hormonal activity, the effect ("control") of these compounds would be minimal.

It is respectfully submitted that the combination of references in the rejection is based, at best, on an obvious to try standard. As the Examiner is aware, that standard is not sufficient to validate a rejection under 35 U.S.C. § 103.

Since the examined claims are now in condition to be allowed, withdrawal of the species requirement and allowance of all claims is respectfully requested.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. According, the Examiner is respectfully requested to pass this application to issue.

Dated: September 9, 2004

Respectfully submitted,

By Edward A. Meilman

Edward A. Meilman
Registration No.: 24,735
DICKSTEIN SHAPIRO MORIN &
OSHINSKY LLP
1177 Avenue of the Americas
New York, New York 10036-2714
(212) 835-1400
Attorney for Applicant

EAM/mgs